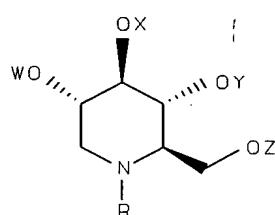


What Is Claimed Is:

1. A method of treating a hepatitis virus infection in a mammal, comprising administering to said mammal a first amount of an N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound of Formula I or a pharmaceutically acceptable salt thereof:



I

wherein:

10 R is selected from the group consisting of arylalkyl, cycloalkylalkyl, and branched or straight chain alkyl having a chain length of C₁ to C₂₀, and

15 W, X, Y, and Z are each independently selected from the group consisting of hydrogen, alkanoyl, aroyl, and trifluoroalkanoyl; and

a second amount of an antiviral compound selected from the group consisting of a nucleoside antiviral compound, a nucleotide antiviral compound, and mixtures thereof,

20 wherein said first and second amounts of said compounds together comprise an anti-hepatitis virus effective amount of said compounds.

2. The method of claim 1, wherein R is a branched or straight chain alkyl having a chain length of C₁ to C₂₀, and W, X, Y, and Z are each hydrogen.

3. The method of claim 2, wherein R is a straight chain alkyl having a chain length of C₁ to C₂₀.

4. The method of claim 3, wherein R is a straight chain alkyl having a chain length of C₂ to C₁₄.

5. The method of claim 4, wherein R is a straight chain alkyl having a chain length of C₆ to C₁₂.

6. The method of claim 5, wherein R is nonyl.

7. The method of claim 1, wherein R is a branched or straight chain alkyl having a chain length of C₁ to C₂₀, and W, X, Y, and Z are each alkanoyl.

8. The method of claim 7, wherein R is a straight chain alkyl having a chain length of C₁ to C₂₀.

9. The method of claim 8, wherein R is a straight chain alkyl having a chain length of C₂ to C₁₄.

10. The method of claim 9, wherein R is a straight chain alkyl having a chain length of C₆ to C₁₂.

11. The method of claim 10, wherein R is nonyl.

12. The method of claim 7, wherein said alkanoyl has a chain length of C₁ to C₂₀.

13. The method of claim 7, wherein said alkanoyl has a chain length of C₂ to C₁₄.

14. The method of claim 7, wherein said alkanoyl has a chain length of C₃ to C₁₀.

15. The method of claim 7, wherein said alkanoyl is butanoyl.

16. The method of claim 7, wherein R is nonyl and W, X, Y, and Z are each butanoyl.

17. The method of claim 1, wherein R is a straight chain alkyl having a chain length of C₁ to C₂₀,

5 W, X, Y, and Z are each hydrogen, and said antiviral compound is a nucleoside antiviral compound.

18. The method of claim 1, wherein R is a straight chain alkyl having a chain length of C₁ to C₂₀,

5 W, X, Y, and Z are each butanoyl, and said antiviral compound is a nucleoside antiviral compound.

19. The method of claim 1, wherein said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is selected from the group consisting of:

5 N-(n-hexyl)-1,5-dideoxy-1,5-imino-D-glucitol;

N-(n-heptyl)-1,5-dideoxy-1,5-imino-D-glucitol;

N-(n-octyl)-1,5-dideoxy-1,5-imino-D-glucitol;

N-(n-octyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

10 N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

N-(n-decyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

N-(n-undecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

15 N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol;
N-(n-decyl)-1,5-dideoxy-1,5-imino-D-glucitol;

N- (n-undecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (n-dodecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (2-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
20 *N*- (4-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (5-methylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (3-propylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-pentylpentylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-butylbutyl) -1,5-dideoxy-1,5-imino-D-glucitol;
25 *N*- (7-methyloctyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (8-methylnonyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (9-methyldecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (10-methylundecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (6-cyclohexylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
30 *N*- (4-cyclohexylbutyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (2-cyclohexylethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-cyclohexylmethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-phenylmethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (3-phenylpropyl) -1,5-dideoxy-1,5-imino-D-glucitol;
35 *N*- (3-(4-methyl)-phenylpropyl) -1,5-dideoxy-1,5-imino-D-
glucitol;
N- (6-phenylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (n-nonyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
40 *N*- (n-decyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (n-undecyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (n-dodecyl) -1,5-dideoxy-1,5-imino-D-glucitol,
45 tetrabutyrate;
N- (2-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (4-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
50 *N*- (5-methylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (3-propylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,

tetrabutyrate;
N-(1-pentylpentylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
55 tetrabutyrate;
N-(1-butylbutyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(7-methyloctyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
60 N-(8-methylnonyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(9-methyldecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(10-methylundecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
65 tetrabutyrate;
N-(6-cyclohexylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(4-cyclohexylbutyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
70 N-(2-cyclohexylethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(1-cyclohexylmethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(1-phenylmethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
75 tetrabutyrate;
N-(3-phenylpropyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(3-(4-methyl)-phenylpropyl)-1,5-dideoxy-1,5-imino-D-
glucitol, tetrabutyrate; and
80 N-(6-phenylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate, and

said nucleoside or nucleotide antiviral compound is selected from the group consisting of:

(+)-cis-5-fluoro-1-[2-(hydroxy-methyl)-[1,3-oxathiolan-5-yl]cytosine;
(-)-2'-deoxy-3'-thiocytidine-5'-triphosphate (3TC);
(-)-cis-5-fluoro-1-[2-(hydroxy-methyl)-[1,3-oxathiolan-5-yl]cytosine (FTC);

(-)2',3', dideoxy-3'-thiacytidine [(-)-SddC] ;
90 1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
iodocytosine (FIAC) ;
1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
iodocytosine triphosphate (FIACTP) ;
1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
95 methyluarcil (FMAU) ;
1-beta-D-ribofuranosyl-1,2,4-triazole-3-carboxamide ;
2',3'-dideoxy-3'-fluoro-5-methyl-dexocytidine (FddMeCyt) ;
2',3'-dideoxy-3'-chloro-5-methyl-dexocytidine (ClddMeCyt) ;
2',3'-dideoxy-3'-amino-5-methyl-dexocytidine (AddMeCyt) ;
100 2',3'-dideoxy-3'-fluoro-5-methyl-cytidine (FddMeCyt) ;
2',3'-dideoxy-3'-chloro-5-methyl-cytidine (ClddMeCyt) ;
2',3'-dideoxy-3'-amino-5-methyl-cytidine (AddMeCyt) ;
2',3'-dideoxy-3'-fluorothymidine (FddThd) ;
2',3'-dideoxy-beta-L-5-fluorocytidine (beta-L-FddC) ;
105 2',3'-dideoxy-beta-L-5-thiacytidine ;
2',3'-dideoxy-beta-L-5-cytidine (beta-L-ddC) ;
2'-deoxy-3'-thia-5-fluorocytosine ;
3'-amino-5-methyl-dexocytidine (AddMeCyt) ;
3'-azido-3'-deoxythymidine (AZT) ;
110 3'-chloro-5-methyl-dexocytidine (ClddMeCyt) ;
9-(2-phosphonyl-methoxyethyl)-2',6'-diaminopurine-2',3'-
dideoxyriboside ;
9-(2-phosphonylmethoxyethyl)adenine (PMEA) ;
acyclovir triphosphate (ACVTP) ;
115 D-carbocyclic-2'-deoxyguanosine (CdG) ;
dideoxy-cytidine ;
dideoxy-cytosine (ddC) ;
dideoxy-guanine (ddG) ;
dideoxy-inosine (ddI) ;
120 E-5-(2-bromovinyl)-2'-deoxyuridine triphosphate ;
fluoro-arabinofuranosyl-iodouracil ;
stavudine ;
2-deoxy-3'-thia-5-fluorocytidine ;
2',3'-dideoxy-guanine ; and

125 2',3'-dideoxy-guanosine.

20. The method of claim 1, wherein said *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is selected from the group consisting of *N*-(*n*-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and *N*-(*n*-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol, tetrabutyrate, and said nucleoside antiviral compound is (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate (3TC).

21. The method of claim 20, wherein said *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is *N*-(*n*-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and said nucleoside antiviral compound is (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate (3TC).

22. The method of claim 1, wherein said first amount of said *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 0.1 mg/kg/day to about 100 mg/kg/day.

23. The method of claim 22, wherein said first amount of said *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 1 mg/kg/day to about 75 mg/kg/day.

24. The method of claim 23, wherein said first amount of said *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 5 mg/kg/day to about 50 mg/kg/day.

25. The method of claim 1, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 0.1 mg/person/day to about 500 mg/person/day.

26. The method of claim 25, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 10 mg/person/day to about 300 mg/person/day.

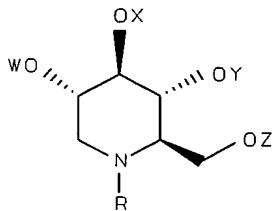
27. The method of claim 26, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 25 mg/person/day to about 200 mg/person/day.

28. The method of claim 27, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 50 mg/person/day to about 150 mg/person/day.

29. The method of claim 1, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 1 mg/person/day to about 50 mg/person/day.

30. The method of claim 1, wherein said hepatitis virus infection is a hepatitis B virus infection.

31. A method of treating a hepatitis B virus infection in a mammal, comprising administering to said mammal from about 0.1 mg/kg/day to about 100 mg/kg/day of an *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound of Formula I:



I

wherein:

R is selected from the group consisting of arylalkyl,
10 cycloalkylalkyl, and branched or straight chain alkyl
having a chain length of C₁ to C₂₀, and

W, X, Y, and Z are each independently selected from
the group consisting of hydrogen, alkanoyl, aroyl, and
trifluoroalkanoyl; and

15 from about 0.1 mg/person/day to about 500
mg/person/day of a compound selected from the group
consisting of a nucleoside antiviral compound, a
nucleotide antiviral, and mixtures thereof.

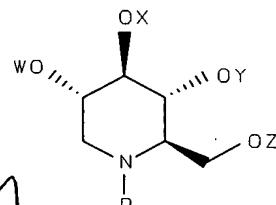
32. The method of claim 31, wherein said
N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is
selected from the group consisting of N-(n-nonyl-)-1,5-
dideoxy-1,5-imino-D-glucitol and N-(n-nonyl-)-1,5-dideoxy-
5 1,5-imino-D-glucitol, tetrabutyrate, and said nucleoside
antiviral agent is (-)-2'-deoxy-3'-thiocytidine-5'-
triphosphate (3TC).

33. The method of claim 32, wherein said
N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is
N-(n-nonyl-)-1,5-dideoxy-1,5-imino-D-glucitol.

34. A method of treating a hepatitis B virus
infection in a human patient, comprising administering to

said human patient from about 0.1 mg/kg/day to about 100 mg/kg/day of *N*-(*n*-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and from about 0.1 mg/person/day to about 500 mg/person/day of (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate.

35. A composition, comprising an *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound of Formula I:



I

5 wherein:

R is selected from the group consisting of arylalkyl, cycloalkylalkyl, and branched or straight chain alkyl having a chain length of C₁ to C₂₀, and

10 W, X, Y, and Z are each independently selected from the group consisting of hydrogen, alkanoyl, aroyl, and trifluoroalkanoyl; and

an antiviral compound selected from the group consisting of a nucleoside antiviral compound, a nucleotide antiviral compound, and mixtures thereof.

36. A pharmaceutical composition, comprising a first amount of an *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound of Formula I:

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cont.

wherein:

5 R is selected from the group consisting of arylalkyl, cycloalkylalkyl, and branched or straight chain alkyl having a chain length of C₁ to C₂₀, and

10 W, X, Y, and Z are each independently selected from the group consisting of hydrogen, alkanoyl, aroyl, and trifluoroalkanoyl; and

15 a second amount of an antiviral compound selected from the group consisting of a nucleoside antiviral compound, a nucleotide antiviral compound, and mixtures thereof, and

15 a pharmaceutically acceptable carrier, diluent, or excipient.

37. The pharmaceutical composition of claim 36, wherein said first and second amounts of said compounds together comprise an anti-hepatitis virus effective amount of said compounds.

38. The pharmaceutical composition of claim 36, wherein R is a branched or straight chain alkyl having a chain length of C₁ to C₂₀, and W, X, Y, and Z are each hydrogen.

39. The pharmaceutical composition of claim 38, wherein R is a straight chain alkyl having a chain length of C₁ to C₂₀.

40. The pharmaceutical composition of claim 39, wherein R is a straight chain alkyl having a chain length of C₂ to C₁₄.

41. The pharmaceutical composition of claim 40, wherein R is a straight chain alkyl having a chain length of C₆ to C₁₂.

42. The pharmaceutical composition of claim 41,
wherein R is nonyl.

43. The pharmaceutical composition of claim 36,
wherein R is a branched or straight chain alkyl having a
chain length of C₁ to C₂₀, and W, X, Y, and Z are each
alkanoyl.

44. The pharmaceutical composition of claim 43,
wherein R is a straight chain alkyl having a chain length
of C₁ to C₂₀.

45. The pharmaceutical composition of claim 44,
wherein R is a straight chain alkyl having a chain length
of C₂ to C₁₄.

46. The pharmaceutical composition of claim 45,
wherein R is a straight chain alkyl having a chain length
of C₆ to C₁₂.

47. The pharmaceutical composition of claim 46,
wherein R is nonyl.

48. The pharmaceutical composition of claim 43,
wherein said alkanoyl has a chain length of C₁ to C₂₀.

49. The pharmaceutical composition of claim 43,
wherein said alkanoyl has a chain length of C₂ to C₁₄.

50. The pharmaceutical composition of claim 43,
wherein said alkanoyl has a chain length of C₃ to C₁₀.

51. The pharmaceutical composition of claim 43,
wherein said alkanoyl is butanoyl.

(+14) (+14)

52. The pharmaceutical composition of claim 43,
wherein R is nonyl and W, X, Y, and Z are each butanoyl.

53. The pharmaceutical composition of claim 36,
wherein

R is a straight chain alkyl having a chain length of
C₁ to C₂₀,

W, X, Y, and Z are each hydrogen, and
said antiviral compound is a nucleoside antiviral
compound.

54. The pharmaceutical composition of claim 36,
wherein

R is a straight chain alkyl having a chain length of
C₁ to C₂₀,

5 W, X, Y, and Z are each butanoyl, and
said antiviral compound is a nucleoside antiviral
compound.

55. The pharmaceutical composition of claim 36,
wherein said N-substituted-1,5-dideoxy-1,5-imino-D-
glucitol compound is selected from the group consisting
of:

5 N-(n-hexyl)-1,5-dideoxy-1,5-imino-D-glucitol;
N-(n-heptyl)-1,5-dideoxy-1,5-imino-D-glucitol;
N-(n-octyl)-1,5-dideoxy-1,5-imino-D-glucitol;
N-(n-octyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

10 N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(n-decyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

15 N-(n-undecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol;
N-(n-decyl)-1,5-dideoxy-1,5-imino-D-glucitol;

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N- (n-undecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (n-dodecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
20 N- (2-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (4-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (5-methylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (3-propylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-pentylpentylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
25 N- (1-butylbutyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (7-methyloctyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (8-methylnonyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (9-methyldecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (10-methylundecyl) -1,5-dideoxy-1,5-imino-D-glucitol;
30 N- (6-cyclohexylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (4-cyclohexylbutyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (2-cyclohexylethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-cyclohexylmethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (1-phenylmethyl) -1,5-dideoxy-1,5-imino-D-glucitol;
35 N- (3-phenylpropyl) -1,5-dideoxy-1,5-imino-D-glucitol;
N- (3-(4-methyl)-phenylpropyl) -1,5-dideoxy-1,5-imino-D-
glucitol;
N- (6-phenylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol;
40 N- (n-nonyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (n-decyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (n-undecyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
45 N- (n-dodecyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (2-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (4-ethylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
50 tetrabutyrate;
N- (5-methylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N- (3-propylhexyl) -1,5-dideoxy-1,5-imino-D-glucitol,

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tetrabutyrate;

55 *N*-(1-pentylpentylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(1-butylbutyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(7-methyloctyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(8-methylnonyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(9-methyldecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

65 *N*-(10-methylundecyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(6-cyclohexylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(4-cyclohexylbutyl)-1,5-dideoxy-1,5-imino-D-glucitol,
70 tetrabutyrate;
N-(2-cyclohexylethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(1-cyclohexylmethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;

75 *N*-(1-phenylmethyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(3-phenylpropyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate;
N-(3-(4-methyl)-phenylpropyl)-1,5-dideoxy-1,5-imino-D-
80 glucitol, tetrabutyrate; and
N-(6-phenylhexyl)-1,5-dideoxy-1,5-imino-D-glucitol,
tetrabutyrate, and
 said nucleoside or nucleotide antiviral compound is
selected from the group consisting of:
85 (+)-*cis*-5-fluoro-1-[2-(hydroxy-methyl)-[1,3-oxathiolan-5-
yl]cytosine;
 (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate (3TC);
 (-)-*cis*-5-fluoro-1-[2-(hydroxy-methyl)-[1,3-oxathiolan-5-
yl]cytosine (FTC);

90 (-)2',3', dideoxy-3'-thiacytidine [(-)-SddC];
1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
iodocytosine (FIAC);
1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
iodocytosine triphosphate (FIACTP);
1-(2'-deoxy-2'-fluoro-beta-D-arabinofuranosyl)-5-
methyluracil (FMAU);
1-beta-D-ribofuranosyl-1,2,4-triazole-3-carboxamide;
2',3'-dideoxy-3'-fluoro-5-methyl-dexocytidine (FddMeCyt);
2',3'-dideoxy-3'-chloro-5-methyl-dexocytidine (ClddMeCyt);
100 2',3'-dideoxy-3'-amino-5-methyl-dexocytidine (AddMeCyt);
2',3'-dideoxy-3'-fluoro-5-methyl-cytidine (FddMeCyt);
2',3'-dideoxy-3'-chloro-5-methyl-cytidine (ClddMeCyt);
2',3'-dideoxy-3'-amino-5-methyl-cytidine (AddMeCyt);
2',3'-dideoxy-3'-fluorothymidine (FddThd);
105 2',3'-dideoxy-beta-L-5-fluorocytidine (beta-L-FddC);
2',3'-dideoxy-beta-L-5-thiacytidine;
2',3'-dideoxy-beta-L-5-cytidine (beta-L-ddC);
2'-deoxy-3'-thia-5-fluorocytosine;
3'-amino-5-methyl-dexocytidine (AddMeCyt);
110 3'-azido-3'-deoxythymidine (AZT);
3'-chloro-5-methyl-dexocytidine (ClddMeCyt);
9-(2-phosphonyl-methoxyethyl)-2',6'-diaminopurine-2',3'-
dideoxyriboside;
9-(2-phosphonylmethoxyethyl)adenine (PMEA);
115 acyclovir triphosphate (ACVTP);
D-carbocyclic-2'-deoxyguanosine (CdG);
dideoxy-cytidine;
dideoxy-cytosine (ddC);
dideoxy-guanine (ddG);
120 dideoxy-inosine (ddI);
E-5-(2-bromovinyl)-2'-deoxyuridine triphosphate;
fluoro-arabinofuranosyl-iodouracil;
stavudine;
2-deoxy-3'-thia-5-fluorocytidine;
125 2',3'-dideoxy-guanine; and

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Sab Pmt

2',3'-dideoxy-guanosine.

56. The pharmaceutical composition of claim 36, wherein said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is selected from the group consisting of N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol, tetrabutyrate, and said nucleoside antiviral compound is (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate (3TC).

57. The pharmaceutical composition of claim 56, wherein said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol.

58. The pharmaceutical composition of claim 36, wherein said first amount of said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 0.1 mg to about 100 mg.

59. The pharmaceutical composition of claim 58, wherein said first amount of said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 1 mg to about 75 mg.

60. The pharmaceutical composition of claim 59, wherein said first amount of said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is in the range of from about 5 mg to about 50 mg.

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61. The pharmaceutical composition of claim 36, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 0.1 mg to about 500 mg.

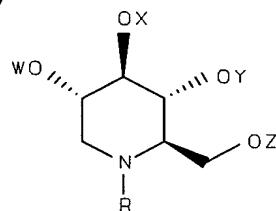
62. The pharmaceutical composition of claim 61, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 10 mg to about 300 mg.

63. The pharmaceutical composition of claim 62, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 25 mg to about 200 mg.

64. The pharmaceutical composition of claim 63, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 50 mg to about 150 mg.

65. The pharmaceutical composition of claim 36, wherein said second amount of said nucleoside or nucleotide antiviral compound, or mixture thereof, is in the range of from about 1 mg to about 50 mg.

66. A pharmaceutical composition for treating a hepatitis B virus infection in a mammal, comprising from about 0.1 mg to about 100 mg of an *N*-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound of Formula I:



wherein:

R is selected from the group consisting of arylalkyl, cycloalkylalkyl, and branched or straight chain alkyl having a chain length of C₁ to C₂₀, and

W, X, Y, and Z are each independently selected from the group consisting of hydrogen, alkanoyl, aroyl, and trifluoroalkanoyl; and

from about 0.1 mg to about 500 mg of a compound selected from the group consisting of a nucleoside antiviral compound, a nucleotide antiviral, and mixtures thereof.

67. The pharmaceutical composition of claim 66, wherein said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is selected from the group consisting of N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol, tetrabutyrate, and said nucleoside antiviral agent is (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate.

68. The pharmaceutical composition of claim 67, wherein said N-substituted-1,5-dideoxy-1,5-imino-D-glucitol compound is N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol.

69. A pharmaceutical composition for treating a hepatitis B virus infection in a human patient, comprising from about 0.1 mg to about 100 mg of N-(n-nonyl)-1,5-dideoxy-1,5-imino-D-glucitol and from about 0.1 mg to about 500 mg of (-)-2'-deoxy-3'-thiocytidine-5'-triphosphate.

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